

K073703

5.3 510(k) Summary Statement

Submitter: American Medical Systems (AMS)
10700 Bren Road West
Minnetonka, MN 55343

Contact Person: Brad Onstad
Phone: 952.930.6139
Fax: 952.930.5785

JAN 30

Device Common Name: Surgical Mesh

Device Trade Name: AMS MiniArc™ Sling System

Device Classification: Class II, 21 CFR Part 878.3300

Classification Name: Surgical Mesh, polymeric (PAH)

Predicate Device: MiniArc Sling System (K071902)

Indications for Use

The AMS MiniArc Sling System is intended for the placement of a suburethral sling for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Device Description

The AMS MiniArc Sling System is a modification of MiniArc Sling System consisting of a sling and a surgical instrument (called a "Needle Passer") for suburethral sling placement. The slings are made from polymeric mesh.

Summary of Testing

The components of the AMS MiniArc Sling System have been tested for performance requirements and found to be substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Mr. Brad Onstad
Senior Regulatory Affairs Specialist
American Medical Systems, Inc.
10700 Bren Road West
MINNETONKA MN 55343

SEP 28 2012

Re: K073703
Trade/Device Name: AMS MiniArc Sling System
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: PAH
Dated: December 28, 2007
Received: December 31, 2007

Dear Mr. Onstad:

This letter corrects our substantially equivalent letter of January 30, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

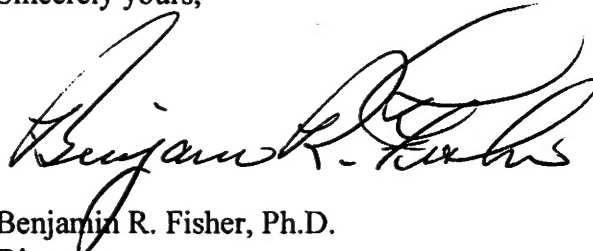
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Benjamin R. Fisher". The signature is fluid and cursive, with the first name "Benjamin" being the most prominent part.

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

5.2 Indications for Use

Indications for Use

510(k) Number (if known):

Device Name: AMS MiniArc Sling System

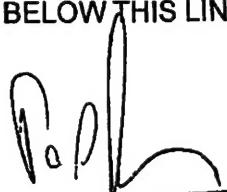
Indications For Use: The AMS MiniArc Sling System is intended for the placement of a suburethral sling for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE
NEEDED)


(Division Staff)
Division of Dental, Restorative
and Neurological Devices
510(k) Number 16073703